December 23, 2003

Sarah Loftus McLallen
Manager, CHEMSTAR
The American Chemistry Council Petroleum Additives Panel
Health, Environmental, and Regulatory Task Group
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio) posted on the ChemRTK HPV Challenge Program Web site on August 21, 2003. I commend The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2,5-Bis(tert-nonyldithio)-1,3,4-thiadiazole

Summary of EPA Comments

The sponsor, the American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group, submitted a test plan and robust summaries to EPA for 2,5-bis(tert-nonyldithio)-1,3,4-thiadiazole (CAS No.89347-09-1), dated August 14, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 21, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. EPA agrees with the submitter's plan to provide measured data following OECD guidelines.

2. Environmental Fate. EPA recommends that the submitter use a level III fugacity model.

3. Health Effects. Adequate data are available for acute and genetic toxicity for the purposes of the HPV Challenge Program. EPA agrees with the submitter's test plan for repeated-dose, reproductive, and developmental toxicity. The submitter needs to address deficiencies in the robust summaries.

4. Ecological Effects. EPA reserves judgement on the adequacy of the acute toxicity data on fish, pending receipt of measured water solubility data. EPA agrees with the proposed aquatic toxicity testing in invertebrates and algae. However, the submitter should consider the results of the planned water solubility test before conducting these tests.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 2,5-bis(tert-nonyldithio)- 1,3,4-thiadiazole Challenge Submission

General

The submitter should note that this chemical is subject to the Canadian Domestic Substances List Categorization and Screening Program and as such information may have been gathered that may address the SIDS-related endpoints for which the submitter intends to develop information.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The submitter's proposal to provide measured data for melting point, boiling point, vapor pressure, and water solubility is adequate for the purposes of the HPV Challenge Program.

Melting point. In table 1 of the test plan, the submitter indicates that melting point is not applicable. However, on page 7, the submitter indicates that testing will be conducted to evaluate this endpoint, along with the other physicochemical endpoints. For the purposes of the HPV Challenge Program, the submitter needs to provide measured melting point data for this chemical following OECD guidelines. Measured data from published sources are acceptable, as long as the submitter identifies the source(s).

Octanol/water partition coefficient. The data provided by the submitter are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for biodegradation and the test plan for photodegradation are adequate for the purposes of the HPV Challenge Program.

Stability in Water. The submitter indicates that it will provide a technical discussion on this endpoint. As there are no data for this endpoint, a technical discussion will be adequate only if this chemical is of a type known to be stable under the test conditions. The technical discussion must be included in the robust summary. Otherwise, the submitter needs to provide measured data following OECD guidelines. An adequate analysis of this endpoint is necessary for evaluating the ecotoxicity endpoints.

Fugacity. The submitter proposes to evaluate fugacity using level I fugacity modeling. Although EPA had previously recommended the use of level I, this model is somewhat limited. EPA now recommends the use of the level III model, which provides a more rigorous level of analysis. EPA believes that values based on a level III fugacity model are more realistic and useful for estimating a chemical's fate in the environment. The submitter should use measured physicochemical data as inputs when running the model. The use of estimated or calculated values introduces uncertainties that then become magnified in modeling applications.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitter's plan to conduct a test according to OECD TG 422 is acceptable to fill data gaps for repeated-dose, reproductive, and developmental toxicity.

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the proposed aquatic toxicity testing in invertebrates and algae. However, the submitter should consider the results of the proposed water solubility test before conducting these tests.

Specific Comments on the Robust Summaries

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitter needs to address the deficiencies below.

Acute toxicity. In the robust summary for the inhalation study, the submitter needs to discuss why the dose is 2.75 mg/L, because OECD TG 403 specifies 5 mg/L as the dose that should be used in a limit test.

Genetic toxicity (chromosomal aberrations). The robust summary states (under "Statistical Analysis") that statistical analysis of the data was not performed. However, the "Remarks field for test conditions" section states that statistically significant differences were used to determine whether a positive response was elicited. Even if analysis was performed only to verify the positive control response, then the type of analysis should be stated.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.